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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,478	02/23/2004	Paul Haefner	GUID.606PA	1794

51294 7590 09/03/2008
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EXAMINER	
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ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/784,478
Filing Date: February 23, 2004
Appellant(s): HAEFNER, PAUL

Paul Sherburne
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/31/2008 appealing from the Office action mailed 10/26/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: based on a typographical error in the final rejection, claims 14 and 15 were erroneously included in the obviousness rejection in view of Yomtov and Joo. These claims were rejected in view of Yomtov, Joo, and Wells.

NEW GROUND(S) OF REJECTION

Although the cited claims have previously been rejected under 35 USC 103(a) as being unpatentable over Yomtov in view of Joo, a new grounds of rejection is presented below under 35 USC 103(a) over Joo in view of Yomtov.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

20050240234	Joo	10-2005
5388578	Yomtov	2-1995
20030032889	Wells	2-2003
Re. 30750	Diack	9-1981

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection under 35 USC 102(b) in view of Diack:

Claim argued separately	Limitation	Disclosure in Diack
1	A signal separation method, comprising:	Diack's method is described generally in the abstract and Figure 1.
	Detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources;	Diack's device detects an electrical signal with non-intrathoracic subcutaneous electrodes 101-103 (Fig. 14 and col. 26, lines 14-21), the electrical signal associated with a plurality of sources (e.g., muscle; col. 19, lines 1-3).
	Receiving information associated with a non-electrophysiological cardiac source;	Diack's device receives information from a non-electrophysiological cardiac source ("phonocardiogram"; Fig. 1, element 22 and col. 5, lines 34-37).
	Separating a signal from the composite electrical signal using source separation;	A "clean" source signal is separated from the composite signal of multiple sources by filtering (col. 19, lines 1-3).
	Verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.	Through the comparison of Table I, Diack's method determines whether the signal is a *normal* cardiac signal (a specific type of cardiac signal) using the two signals.

17	Further comprising detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological source.	The correlation of the two signals is performed in Table I, and a cardiac condition is determined (e.g., a condition suitable for no therapy, defibrillation therapy, or pacing therapy).
30	An implantable device, comprising:	Diack's device is described generally in the abstract and Figure 1, and disclosed as at least partially implantable at col. 26, lines 14-21.
	Means for subcutaneously detecting a composite electrical signal associated with a plurality of signal sources;	Diack's device detects an electrical signal with non-intrathoracic subcutaneous electrodes 101-103 (Fig. 14 and col. 26, lines 14-21), the electrical signal associated with a plurality of sources (e.g., muscle; col. 19, lines 1-3).
	Means for subcutaneously detecting non-electrical cardiac activity;	Diack's device receives information from a non-electrophysiological cardiac source ("phonocardiogram"; Fig. 1, element 22 and col. 5, lines 34-37).
	Means for separating a signal from the composite electrical signal using source separation;	A "clean" source signal is separated from the composite signal of multiple sources by filtering (col. 19, lines 1-3).
	Means for determining whether or not the separated signal is a cardiac electrical signal using the detected non-electrical cardiac activity.	Through the comparison of Table I, Diack's method determines whether the signal is a *normal* cardiac signal (a specific type of cardiac signal) using the two signals.
31	Wherein determining means comprises means for performing a time correlation between the separated signal and the signal associated with the detected non-electrical cardiac activity.	The correlation of the two signals is performed in Table I, and a cardiac condition is determined (e.g., a condition suitable for no therapy, defibrillation therapy, or pacing therapy). The signals are time-correlated because they are compared simultaneously (col. 5, lines 42-68).

Rejections under 35 USC 103(a) over Yomtov in view of Joo:

Claim	Limitation	Teaching	Motivation to modify
1	A signal separation	Yomtov generally	

	method, comprising:	describes the method in the abstract.	
	Detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources;	Yomtov shows subcutaneous non-intrathoracic placement in Figure 1 and Figure 2 shows that the acquired signal comprises a variety of features (which arise from various sources in the heart).	
	Receiving information associated with a non-electrophysiological cardiac source;	Yomtov discloses using a second signal to verify sensed events at column 17, lines 40-56, but does not disclose that this is non-electrophysiological.	Joo teaches a device using a second, non-electrophysiological cardiac source to provide the predictable result of providing redundancy in recognizing a cardiac pulse using conventional transductions means susceptible to different forms of noise to provide accurate detection of arrhythmia.
	Separating a signal from the composite electrical signal using source separation;	Yomtov discloses separating the R-wave signal from the composite signal of features from a variety of sources in the heart at element 96.	
	Verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.	Yomtov discloses verifying that the separated signal is a cardiac signal using the second signal (col. 17, lines 40-56), but does not disclose that this is a non-electrophysiological signal.	Joo teaches a device using a second, non-electrophysiological cardiac source to provide the predictable result of providing redundancy in recognizing a cardiac pulse using conventional transductions means susceptible to different forms of noise to provide accurate detection of arrhythmia.
6	Wherein verifying that	Yomtov defines a time	

	the separated signal is the cardiac signal comprises providing a detection window defined by a start time preceding the temporal location of a peak heart sound.	window comprising a window 8 ms before the QRS complex and 8 ms after the QRS complex (col. 20, lines 38-62). As the heart sound is a mechanical manifestation resulting from the electrical activity of the ECG, Yomtov inherently meets this limitation (see Fig. 1 in Joo).	
11	Wherein verifying that the separated signal is the cardiac signal comprises providing a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source.	Yomtov discloses that the first signal is correlated to the second signal (col. 17, lines 40-56), but not that the second signal is non-electrophysiological.	Joo teaches a device using a second, non-electrophysiological cardiac source to provide the predictable result of providing redundancy in recognizing a cardiac pulse using conventional transductions means susceptible to different forms of noise to provide accurate detection of arrhythmia.
12	Further comprising determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source.	Yomtov discloses determining a time separation between the R-wave detector signal and the ECG (second) signal at column 15, lines 22-36).	
13	Wherein the time separation is used to identify the cardiac source.	Yomtov discloses determining a time separation between the R-wave detector signal and the ECG (second) signal at column 15, lines 22-36), and this is used to confirm the cardiac signal.	
17	Further comprising detecting a cardiac	Yomtov discloses that the two signals are correlated	

	condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological source.	at column 17, lines 40-56.	
30	An implantable device, comprising:	Yomtov generally describes the device in the abstract.	
	Means for subcutaneously detecting a composite electrical signal associated with a plurality of signal sources;	Yomtov shows subcutaneous non-intrathoracic placement in Figure 1 and Figure 2 shows that the acquired signal comprises a variety of features (which arise from various sources in the heart).	
	Means for subcutaneously detecting non-electrical cardiac activity;	Yomtov discloses using a second signal to verify sensed events at column 17, lines 40-56, but does not disclose that this is non-electrophysiological.	Joo teaches a device using a second, non-electrophysiological cardiac source to provide the predictable result of providing redundancy in recognizing a cardiac pulse using conventional transductions means susceptible to different forms of noise to provide accurate detection of arrhythmia.
	Means for separating a signal from the composite electrical signal using source separation;	Yomtov discloses separating the R-wave signal from the composite signal of features from a variety of sources in the heart at element 96.	
	Means for determining whether or not the separated signal is a cardiac electrical signal	Yomtov discloses verifying that the separated signal is a cardiac signal using the	Joo teaches a device using a second, non-electrophysiological cardiac source to provide

	using the detected non-electrical cardiac activity.	second signal (col. 17, lines 40-56), but does not disclose that this is a non-electrophysiological signal.	the predictable result of providing redundancy in recognizing a cardiac pulse using conventional transductions means susceptible to different forms of noise to provide accurate detection of arrhythmia.

Rejections under 35 USC 103(a) over Joo in view of Yomtov:

Claim	Limitation	Teaching	Motivation to modify
1	A signal separation method, comprising:	Joo generally describes the method in the abstract.	
	Detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources;	Joo discloses acquiring an electrical signal associated with a plurality of sources (par. 0059), but does not disclose subcutaneous non-intrathoracic placement.	Yomtov teaches subcutaneous non-intrathoracic placement to provide the predictable results of a permanent defibrillator that avoids the complications of intracardiac placement.
	Receiving information associated with a non-electrophysiological cardiac source;	Joo discloses receiving a non-electrophysiological signal (element 250).	
	Separating a signal from the composite electrical signal using source separation;	Joo discloses separating the signal by filtering (par. 0059), and further discloses various other separation strategies for the cardiac signal (par. 0126-0129)	
	Verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological	Joo discloses verifying that the separated signal is a cardiac signal using both acquired signals (element 256).	

	cardiac source information.		
30	An implantable device, comprising:	Joo generally describes the device in the abstract.	
	Means for subcutaneously detecting a composite electrical signal associated with a plurality of signal sources;	Joo discloses acquiring an electrical signal associated with a plurality of sources (par. 0059), but does not disclose subcutaneous non-intrathoracic placement.	Yomtov teaches subcutaneous non-intrathoracic placement to provide the predictable results of a permanent defibrillator that avoids the complications of intracardiac placement.
	Means for subcutaneously detecting non-electrical cardiac activity;	Joo discloses receiving a non-electrophysiological signal (element 250).	
	Means for separating a signal from the composite electrical signal using source separation;	Joo discloses separating the signal by filtering (par. 0059), and further discloses various other separation strategies for the cardiac signal (par. 0126-0129)	
	Means for determining whether or not the separated signal is a cardiac electrical signal using the detected non-electrical cardiac activity.	Joo discloses verifying that the separated signal is a cardiac signal using both acquired signals (element 256).	

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Diack et al. (US Re. 30,750, hereinafter "Diack").

In regards to claims 1 and 30, Diack discloses detecting a composite electrical signal and separating a signal from the composite signal using source separation (Fig. 14, element 110 and col. 18, line 66), receiving information associated with a non-electrophysiological source (Fig. 14, element 122), and verifying that the separated signal is a cardiac signal, e.g. a "normal" cardiac signal, using both signals (Table 1). Further, the composite signal is acquired at a subcutaneous non-intrathoracic location (col. 26, line 17).

In regards to claims 4, 7, 8, and 10, the non-electrophysiological cardiac source comprises acoustic information, blood flow information, pulse pressure information, and impedance information (col. 2, line 26).

In regards to claims 16 and 17, a cardiac condition is detected using a correlation between the signals (abstract and Table 1).

In regards to claims 18, 19 and 34-36, a cardiac arrhythmia is detected and treated (abstract and Table 1).

In regards to claim 31, because the two signals are "and-ed", the two signals are time-correlated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 16-19 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yomtov et al. (US 5,388,578, hereinafter "Yomtov") in view of Joo et al. (US 2005/0240234, hereinafter "Joo"). Yomtov discloses the essential features of the claimed invention including the following:

In regards to claims 1, 4-10, and 30, Yomtov discloses detecting a composite electrical signal at a subcutaneous non-intrathoracic location (Fig. 1), separating a signal from the composite signal and verifying that the separated signal is a cardiac signal using a second cardiac source signal (element 96; col. 17, line 40; and Figs. 8A and 8B). Yomtov does not disclose that the second cardiac source signal is a non-electrophysiological signal comprising acoustic emission information, blood flow information, pulse pressure information, pulse oximetry information or transthoracic impedance information. Joo teaches of utilizing both an electrophysiological and non-electrophysiological signal comprising acoustic emission information, blood flow information, pulse pressure information, pulse oximetry information or transthoracic impedance information to confirm a cardiac pulse (abstract and par. 0104) to provide redundancy in recognizing a cardiac pulse using conventional equivalent transduction means susceptible to different forms of noise, thusly providing highly accurate arrhythmia recognition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Yomtov's invention by utilizing both an electrophysiological and non-electrophysiological signal to confirm a cardiac pulse to provide the predictable result of providing redundancy in recognizing a

cardiac pulse using conventional equivalent transduction means susceptible to different forms of noise, thusly providing highly accurate arrhythmia recognition.

In regards to claims 2, 3, 11, and 31-33, Yomtov discloses that the second signal is used to define a detection window comprising a QRS complex through correlation (col. 14, line 24).

In regards to claims 12 and 13, a peak separation is determined and used to identify a cardiac signal (col. 15 line 23).

In regards to claims 16, 17, 18, 34, and 36, a cardiac condition is detected using a correlation between the two signals (see above) wherein the condition is arrhythmia (col. 3, line 23).

In regards to claims 19 and 35, the arrhythmia is treated (col. 8, line 43). Because defibrillation protection circuitry is provided, a defibrillator must be present, whether part of device 32, or external to device 32.

Claims 1-13, 16-19, and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joo et al. (US 2005/0240234, hereinafter "Joo") in view of Yomtov et al. (US 5,388,578, hereinafter "Yomtov").

In regards to claims 1, 17, 30, and 31, Joo discloses the essential features of the claimed invention including detecting a composite electrical signal associated with a plurality of sources (Fig. 14, element 246 and par. 0059; the ECG electrical signal is filtered), receiving information associated with a non-electrophysiological cardiac source (element 250), separating a signal from the composite signal using source separation

(par. 0059, the signal is filtered); and verifying that the separated signal is a cardiac signal by correlating the separated and non-electrophysiological source information (element 256). Joo further teaches that the method can be used in other devices (par. 0051), but does not disclose that the electrical signal is detected at a subcutaneous non-intrathoracic location. Yomtov teaches a system that verifies signals in a subcutaneous non-intrathoracic location to provide the predictable results of avoiding the complications associated with implanting electrodes directly into the heart. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Joo's invention by detecting signals in a subcutaneous non-intrathoracic location to provide the predictable results of avoiding the complications associated with implanting electrodes directly into the heart.

In regards to claims 2, 11, 32, and 33, the verification step is performed over a detection window defined by a start and stop time determined with the non-electrophysiological signal (par. 0125-0126).

In regards to claim 3, the method further comprises detecting a QRS complex during the window (par. 0124).

In regards to claims 4 and 5, the non-electrophysiological signal comprises acoustic source information (par. 0056), and the source information comprises the temporal location of peak heart sounds (par. 0078).

In regards to claims 6, 12 and 13, a detection window is defined by a start time preceding the temporal location of the peak heart sound (par. 0076; the "timing of the S1 or S2 heart sound in relation to an R-wave" is shown in Fig. 1).

In regards to claims 7 and 8, heart sounds arise from blood flow turbulence, thus inherently comprise blood-flow/pulse information.

In regards to claims 9 and 10, Joo discloses that oximetry or impedance can also be used as a sensed variable (pars. 0104 and 0107).

In regards to claim 16, 18, 19, 34, 35, and 36, a cardiac arrhythmia (rhythm) is determined and treated (abstract).

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yomtov in view of Joo (or Diack or Joo in view of Yomtov), as applied to claim 1 above, and further in view of Wells (US 2003/0032889 hereinafter "Wells"). The modified invention of Yomtov (or Diack or Joo) discloses the essential features of the claimed invention except for separating signals using blind source separation and independent component analysis. Wells teaches of identifying constituent signals using blind source separation and independent component analysis (par. 0007) to separate signals where little is know of their individual contributions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Yomtov's (or Diack's or Joo's) invention by identifying constituent signals using blind source separation and independent component analysis to provide the predictable result of separating signals where little is know of their individual contributions.

(10) Response to Argument

Appellant argued that Diack fails to disclose separating a signal from a composite signal using source separation because Diack merely uses bandpass filtering. The Examiner maintains the previously asserted position that bandpass filtering is "source separation" because it removes unwanted sources (noise) from the desired source. Even if this separation is performed by frequency, the pass-band is chosen such that a source of a desired frequency is acquired, while the undesired frequency source is attenuated. Appellant also noted that Diack discloses that the filter reduces the effects of muscle potentials and external interferences at column 19, lines 1-3, instead of totally blocking. However, the claim language does not require total attenuation, but only separation. The Examiner is of the position that reduction of external interference is still source separation because the desired signal is discerned from the undesired noise. Due to an absence of any “special definitions" in the specification, the Examiner maintains the broadest reasonable interpretation of “source separation.”

Appellant further argued that Diack does not perform the “verification” step, but merely uses two signals to initiate therapy, assuming that the EKG signal is a cardiac signal for the entire algorithm. However, the Examiner is interpreting the verifying step to be verifying that the signal is an abnormal cardiac signal or normal cardiac signal. In other words, the Examiner is considering Diack’s “abnormal cardiac signal” to be a species of the “cardiac signal” genus, thus reading on the claim language. Further both signals “verify” each other to confirm the various treatable conditions.

Appellant further argued, with respect to claims 17 and 31, that the signals are not time correlated. However, the signals are "time-correlated" because they are compared simultaneously. As electrical activity is ascertained at the same time as sound, the signals are correlated in time at the time of comparison/verification.

Appellant further argued that Yomtov's R-wave detector does not meet the "source separation" limitation because ECG signals, whether intrinsic or paced, come from the heart. However, the R-wave detector separates the R-wave source form the other ECG features (such as P, Q, S, and T waves), and further, paced pulses come from the stimulator source and paced beats come from myocardial tissue. Although Yomtov does not disclose the phrase "source separation," the Examiner maintains that this separation of the R-wave from the other features of the ECG reads on the claim language.

Appellant further argued that Yomtov lacks disclosure of verifying that a separated signal is a cardiac signal, but merely switches channels because of noise. The Examiner maintains that Yomtov's disclosure at column 17, lines 40-48 provides this teaching because the second channel is utilized to confirm whether the first channel's cardiac signal is valid.

Appellant further argued, with respect to claim 6, that Yomtov does not provide a detection window defined by a start time preceding the temporal location of a peak heart sound because Yomtov does not address non-electrophysiological signals. However, the claim language does not require an actual determination of a peak heart sound, only that the window has a start time preceding the peak heart sound. As the heart sound is

a mechanical manifestation resulting from the electrical activity of the ECG, Yomtov inherently meets this limitation (see Fig. 1 in Joo, which shows the inherent time relationship between the QRS complex and heart sound).

Appellant further argued, with respect to claims 11 and 17 that Yomtov fails to provide a detection window in which the cardiac and non-electrophysiological signal are correlated. However, Joo is relied upon for the teaching of a cardiac and non-electrophysiological signal, and Yomtov is provided for the teaching of correlating two signals in the time window.

In regards to claims 12 and 13, the Examiner maintains that retrieving a time separation from memory is "determining a time separation." Joo is relied upon for the teaching of utilizing a cardiac and non-electrophysiological source.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be

relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Michael Kahelin/

Examiner, Art Unit 3762

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

***/Frederick R Schmidt/

Director, Technology Center

Conferees:

/George R Evanisko/

Primary Examiner, Art Unit 3762

/Angela D Sykes/

Supervisory Patent Examiner, Art Unit 3762

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